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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

M2839n

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 4, 1999

Richard T. Lofstad, Jr., President
Long Island Fish Exchange
109 South Street
New York, NY 10038

Ref: NYK 1999-59

Dear Mr. Lofstad:

An inspection of your facility located at 109 South Street, New York, New York, was conducted on April 22 and 27, 1999 by the U.S. Food and Drug Administration (FDA). The inspection revealed that raw fish such as king mackerel, processed and stored at your facility, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. They are adulterated because they were processed and held under conditions contrary to Title 21 Code of Federal Regulations (CFR), Part 123, which constitute insanitary conditions whereby they may have been rendered injurious to health.

As we explained in previous letters to you, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: **(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing and storing of refrigerated histamine forming species of fish, including king mackerel, deviates from the regulations contained in 21 CFR 123 as follows:

1. Failure to implement the monitoring procedures specified in your HACCP plan for the receipt, display, and cooler storage of histamine forming species, including king mackerel [21 CFR 123.6(b)].

2. Failure to maintain records that document the monitoring of the critical control points identified in your HACCP plan [21 CFR 123.6(c)(7). HACCP monitoring records for the critical control points of receiving, display, and storage are missing for the period of August

1998 through April 1999. For example, there are no records to indicate that the firm is monitoring the adequacy of ice for histamine forming species held outside for street display.

3. The corrective action listed in your HACCP plan for histamine forming species is inadequate [21 CFR 123.7(a)(1)]. Your firm's corrective action plan describes taking the core temperature of the fish. This is not sufficient to address the acceptability and safety of the affected product. Histamine testing needs to be performed or the product should be rejected or diverted to a non-food use. Additionally, the HACCP plan fails to ensure that the cause of the deviation at the receiving and display critical control points are corrected.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your facility is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Fabio L. Mattiasich, Compliance Officer. Mr. Mattiasich can be reached at (718) 340-7000 ext. 5292.

Sincerely,

Brenda J. Holman
District Director